

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
[Docket No. 01E-0403]

DMB  
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Certifier N. Hawkins

Determination of Regulatory Review Period for Purposes of Patent  
Extension; VALCYTE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VALCYTE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

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Office of Regulatory Policy (HFD-013),  
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301-827-3460.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g) (1) (B).

FDA recently approved for marketing the human drug product VALCYTE (valganciclovir hydrochloride). VALCYTE is indicated for treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome (AIDS). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VALCYTE (U.S. Patent No. 6,083,953) from Syntex, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 31, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VALCYTE represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VALCYTE is 2,101 days. Of this time, 1,919 days occurred during the testing phase of the regulatory review period, while 182 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective: June 30, 1995. The applicant claims July 26, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND

effective date was June 30, 1995, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: September 29, 2000. The applicant claims September 28, 2000, as the date the new drug application (NDA) for VALCYTE (NDA 21-304) was initially submitted. However, FDA records indicate that NDA 21-304 was submitted on September 29, 2000.

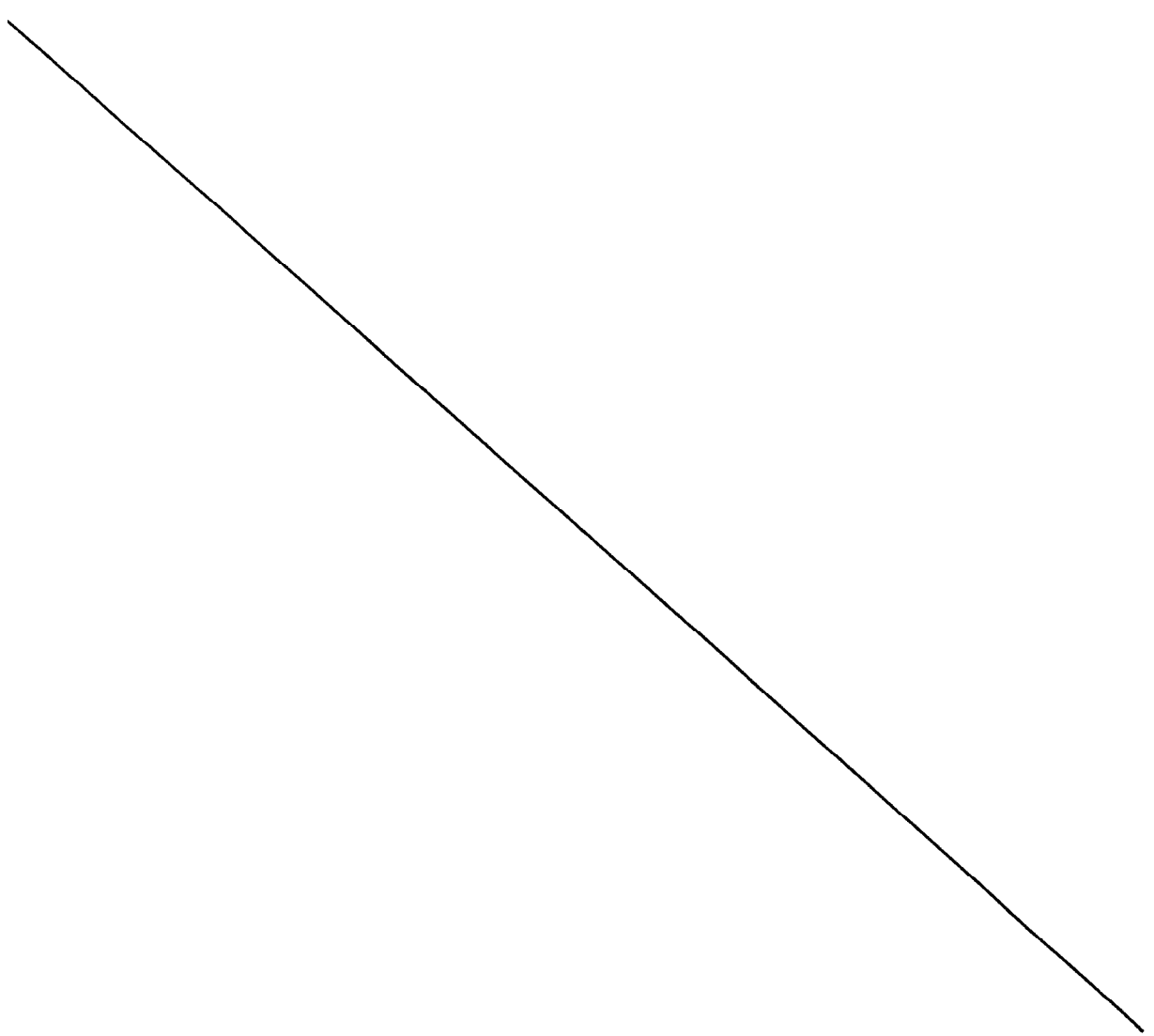
3. The date the application was approved: March 29, 2001. FDA has verified the applicant's claim that NDA 21-304 was approved on March 29, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 226 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments and ask for a redetermination by [insert date 60 days after date of publication in the FEDERAL REGISTER]. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by [insert date 180 days after date of publication

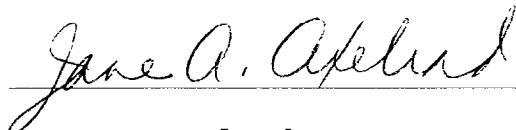
in the FEDERAL REGISTER]. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the



docket number found in brackets in the heading of this document.  
Comments and petitions may be seen in the Dockets Management  
Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1/13/03.  
January 13, 2003.



Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

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